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MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO  
666 THIRD AVENUE  
NEW YORK, NY 10017

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/700,177

Applicant(s)

LINDAHL ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 58,60-70,73,75-77,81-84,86-93,95 and 98-121 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 58, 60-70, 73, 75-77, 81-84, 86-93, 95 and 98-121 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment, remarks and supporting documentation for chemical reaction, all filed 10/07/05. Claims 58, 60-70, 73, 75-77, 81-84, 86-93, 95 and 98-121 are pending, of the pending claims, claims 107-121 are new. Upon further review many methods for the preparation of biologically active composition are identified.

#### ***Election/Restrictions***

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- i. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dissolving biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.
- ii. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dissolving biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.
- iii. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dissolving biologically active agent in the carrier starting

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substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.

iv. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dissolving biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.

v. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more different carrier starting substance, dissolving biologically active agent in the mixture of two or more carrier starting substance, and subjecting the mixture of two or more carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.

vi. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more different carrier starting substance, dissolving biologically active agent in the mixture of two or more carrier starting substance, and subjecting the mixture of two or more carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.

vii. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more carrier starting substance, dissolving biologically active

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agent in the carrier starting substance, and subjecting the mixture or two or more carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.

viii. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more carrier starting substance, dissolving biologically active agent in the carrier starting substance, and subjecting the mixture or two or more carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.

ix. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dispersing biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.

x. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dispersing biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.

xi. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dispersing biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of

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time to cleave a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.

xii. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, dispersing biologically active agent in the carrier starting substance, and subjecting the carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.

xiii. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more different carrier starting substance, dispersing biologically active agent in the mixture of two or more carrier starting substance, and subjecting the mixture of two or more carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.

xiv. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more different carrier starting substance, dispersing biologically active agent in the mixture of two or more carrier starting substance, and subjecting the mixture of two or more carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.

xv. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more carrier starting substance, dispersing biologically active agent in the carrier starting substance, and subjecting the mixture or two or more carrier starting

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substance to a chemical reaction over a period of time to cleave a covalent bond; and wherein the chemical reaction is initiated in the presence of the biological agent.

xvi. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more carrier starting substance, dispersing biologically active agent in the carrier starting substance, and subjecting the mixture or two or more carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond; and wherein the chemical reaction is initiated in the absence of the biological agent.

From new claim 107

xvii. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, adding biologically active agent to the carrier starting substance to form a composition, and subjecting the composition of the carrier starting substance and the biologically active agent to a chemical reaction over a period of time to form a covalent bond.

xviii. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, subjecting the carrier starting substance to a chemical reaction over a period of time to form a covalent bond, adding biologically active agent to the carrier starting substance to form a composition, which is subjected to further chemical reaction.

xix. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, adding biologically active agent to the carrier starting substance to form a composition, and subjecting the composition of the carrier starting substance and the biologically active agent to a chemical reaction over a period of time to cleave a covalent bond.

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xx. A process of preparing a biologically active composition, the process comprises providing a carrier starting substance, subjecting the carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond, adding biologically active agent to the carrier starting substance to form a composition, which is subjected to further chemical reaction.

xxi. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more different carrier starting substance, adding biologically active agent to the mixture of two or more carrier starting substance to form a composition, and subjecting the composition of the mixture of two or more carrier starting substance and the biological agent to a chemical reaction over a period of time to form a covalent bond.

xxii. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more different carrier starting substance, adding biologically active agent to the mixture of two or more carrier starting substance to form a composition, and subjecting the composition of the mixture of two or more carrier starting substance and the biological agent to a chemical reaction over a period of time to cleave a covalent bond.

xxiii. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more carrier starting substance, subjecting the mixture or two or more carrier starting substance to a chemical reaction over a period of time to form a covalent bond; and adding biologically active agent to the mixture of two or more carrier starting substance at a predetermined time to form a composition, which is subjected to further chemical reaction.

xxiv. A process of preparing a biologically active composition, the process comprises providing a mixture of two or more carrier starting substance, subjecting the mixture or two or



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more carrier starting substance to a chemical reaction over a period of time to cleave a covalent bond; and adding biologically active agent at a predetermined time to the mixture of two or more carrier starting substance to form a composition, which is subjected to further chemical reaction.

From new claim 108

xxv. A method of preparing a biologically active composition, the method comprises providing a composition comprising carrier starting substance in which biologically active agent is dissolved, and subjecting the composition of carrier starting substance and the biologically active agent to a chemical reaction over a period of time to form a covalent bond.

xxvi. A method of preparing a biologically active composition, the method comprises providing a composition comprising carrier starting substance in which biologically active agent is dissolved, and subjecting the composition of carrier starting substance and the biologically active agent to a chemical reaction over a period of time to cleave a covalent bond.

xxvii. A method of preparing a biologically active composition, the method comprises providing a composition comprising carrier starting substance in which biologically active agent is dispersed, and subjecting the composition of carrier starting substance and the biologically active agent to a chemical reaction over a period of time to form a covalent bond.

xxviii. A method of preparing a biologically active composition, the method comprises providing a composition comprising carrier starting substance in which biologically active agent is dispersed, and subjecting the composition of carrier starting substance and the biologically active agent to a chemical reaction over a period of time to cleave a covalent bond.

From new claims 108 and 109

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xxix. A method of preparing a biologically active composition, the method comprises providing a composition comprising mixture of two or more different carrier starting substance in which is dissolved biologically active agent, and subjecting the composition of mixture of two or more carrier starting substance and biologically active agent to a chemical reaction over a period of time to form a covalent bond.

xxx. A method of preparing a biologically active composition, the method comprises providing a composition comprising carrier starting substance in which biologically active agent is dissolved, and subjecting the composition of carrier starting substance and the biologically active agent to a chemical reaction over a period of time to cleave a covalent bond.

xxxi. A method of preparing a biologically active composition, the method comprises providing a composition comprising carrier starting substance in which biologically active agent is dispersed, and subjecting the composition of carrier starting substance and the biologically active agent to a chemical reaction over a period of time to form a covalent bond.

xxxii. A method of preparing a biologically active composition, the method comprises providing a composition comprising carrier starting substance in which biologically active agent is dispersed, and subjecting the composition of carrier starting substance and the biologically active agent to a chemical reaction over a period of time to cleave a covalent bond.

From new claim 110

xxxiv. A method of preparing biologically active composition in which a biologically active agent is dissolved and/or dispersed, the method comprises initiating a chemical reaction on a carrier starting substance, the chemical reaction results in the formation of covalent bonds;

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adding a biological agent to the carrier starting substance, that has undergone a chemical reaction, to form a composition; and subjecting the composition to further chemical reaction.

xxxv. A method of preparing biologically active composition in which a biologically active agent is dissolved and/or dispersed, the method comprises initiating a chemical reaction on a carrier starting substance, the chemical reaction results in the cleavage of covalent bonds; adding a biological agent to the carrier starting substance, that has undergone a chemical reaction, to form a composition; and subjecting the composition to further chemical reaction.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. It is also noted that “initiating a chemical” reaction appears to be new matter, not supported by the specification as originally filed. Secondly, species xxxiv and xxxv were not originally elected and may be restricted out in view of election by original presentation. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Election of any of the species from i to xxxiii, requires that applicants elect a single chemical reaction from the list of possible chemical reactions recited, namely, etherification, esterification, hydrolysis, substitution, addition, elimination, oligomerization or polymerization; and when one or more chemical reactions are contemplated for the species, applicants must specify/elect the contemplated reaction couple. Furthermore, applicants are required to elect a single disclosed carrier starting substance from the list recited, namely, monomers, acids,

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alcohols, ketones, aldehydes, amines, amides, anhydrides, lactides, glycolides, saccharides, acrylic or acrylamide, monomers of polyethylene oxide diacrylate, cyanoacrylate, acrylate saccharides, acrylate lactate, acrylate glycolate, isocyanate, ethylene oxide, propylene oxide. Pyrrolidone, PEO-diacrylate, ethylene-vinylacetate, monomers of organic siloxanes and oligomers; and if mixture of two or more different carrier starting substances is elected, then applicants must specifically identify/elect the carrier starting substances that comprise the mixture. Applicants are further required to elect a specific disclosed biologically active agent.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner: Species i to xxxiii are different.

The following claim(s) are generic: 87, 107, 108, 109, 110 and 114.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Hydrolysis is not the same reaction as polymerization or etherification or substitution or addition reaction. A single carrier starting substance differs in scope from a mixture comprising two or more carrier substances.

4. A telephone call was not made to applicants to request an oral election to the above restriction requirement because of the complexity of the requirement.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

